8/4/2004

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AMPHYL®

[DISINFECTANT] • [DEODORANT] • [DETERGENT]

[TUBERCULOCIDAL*] [PSEUDOMONACIDAL*] [GERMICIDAL*] [FUNGICIDAL*] [VIRUCIDAL*] AMPHYL* DISINFECTS AND DEODORIZES IN ONE OPERATION.

[GERMICIDAL*] [STAPHYLOCIDAL] [(including methicillin and gentamicin resistant staphylococcus)]

[SALMONELLACIDAL] [PSEUDOMONACIDAL] [TUBERCULOCIDAL]

[FUNGICIDAL*] [Against pathogenic fungi]

[VIRUCIDAL*] [Against the following viruses –] [Human Immunodeficiency Virus Type 1 (HIV-

1)(AIDS Virus)] [Herpes Simplex Type 1] [Influenza A2 (Hong Kong)] [and] [Vaccinia]

*On hard, nonporous environmental surfaces

[FOR HOSPITAL USE]

ART OF YOUR INFECTION CONTROL PROGRAM]

[FOR USE [ONLY] IN INSTITUTIONAL AND INDUSTRIAL FACILITIES]

[DILUTE AT 1:200] [OR] [1:100]

[[FOR USE] [CAN BE USED] [AS] [IN] [USEFUL AS] PART OF [AN] [A FACILITY'S] [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[HELPS COMPLETE] [ADDS TO] [ROUNDS OUT] A FACILITY'S [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[WORKS] [IS COMPATIBLE] [WITH OTHER RECKITT BENCKISER PROFESSIONAL PRODUCTS] [IN COMBATING CROSS CONTAMINATION] [ON ENVIRONMENTAL SURFACES] [IN THE HEALTH CARE ENVIRONMENT.]

[IFOR] [USE BY ENVIRONMENTAL SERVICES] [IN COMBATING CROSS CONTAMINATION] [IN A HEALTH RE FACILITY.]]

ACTIVE INGREDIENTS:

†Includes detergents, other cleaning agents and no phosphorous compounds.

-AUG - 4 2004 Under the Federal Insecticide, Fungicide, and Rogenfluide Act as annonad, for the positicide, registered under 43 EPA Reg. No. 6

KEEP OUT OF REACH OF CHILDREN

DANGER

Corrosive. Causes eye damage and skin irritation.

See Back (Side) Panel for First Aid and Additional Precautionary Statements

EPA Reg. No. 675-43

EPA Est. No. {Insert Establishment number}

Net Contents: {Insert container size}

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DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[AMPHYL®] [This product] is recommended for use on hard, nonporous environmental surfaces in:

- [hospitals]
- [nursing homes]
- [dental offices]
- [doctors' offices]

[AMPHYL®] [This product] [It] disinfects hard, nonporous [environmental] surfaces such as:

• [floors]

• [wheelchairs]

• [furniture]

• [walls]

• [patient bed frames]

• [counters]

• [bathroom fixtures]

• [bedside tables]

• [surgical instruments]

• [medical lamps]

• [dental instruments]

• [stands]

• [trays]

MPHYL®] [This product] is a concentrate. Always dilute in accordance with label instructions. Thoroughly preclean all soiled surfaces with [AMPHYL®] [this product] prior to disinfecting, as described [below] [on side panel].

NOTE: Prepare fresh AMPHYL® solution for each use. If a freshly prepared 0.5% AMPHYL® solution is not to be utilized immediately, add 2 oz. of Isopropyl alcohol to each quart of AMPHYL® solution to maintain clarity.

To prepare proper dilutions in required quantities, add [this product] full strength [AMPHYL®] to water as below.

[DILUTION CHART]

CORRECT SOLUTION STRENGTH	AMPHYL®	WATER
0.5% (1:200)	5cc (1 tsp.)	1 quart
	20cc (4 tsp.)	1 gallon
	40cc (1-1/3 oz.)	2 gallons
[1.0% (1:100)]	[10cc (2 tsp.)]	[1 quart]
	[40cc (1-1/3 oz.)]	[1 gallon]
	[80cc (2-2/3 oz.)]	[2 gallons]

ONE TABLESPOONFUL IS EQUIVALENT TO 1/2 FLUID OUNCE OR 15 CC.

FOR GENERAL CLEANING: Use a 0.5% solution for lightly soiled areas [and a 1% solution for more difficult soil conditions.]

FOR [USE IN HEALTHCARE SETTINGS] [USE AS A HOSPITAL DISINFECTANT] [HOSPITAL DISINFECTION] (Including Tuberculocidal effectiveness): When required, remove heavy soil and gross filth prior to disinfection as per above cleaning instructions. Floors, walls and [hard, nonporous] environmental surfaces should be mopped, wiped, or scrubbed with the recommended solution [1:200], maintaining a thoroughly wet surface for 10 minutes and allowed to air dry. Discard used solution daily or more often if soiling is evident. [AMPHYL®] [This product] is effective in 10 minutes at 20°C (68°F). [For tuberculocidal activity 0.5% AMPHYL® is effective in 10 minutes at 20°C (68°F).]

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INSTRUMENT[S] [DECONTAMINATION]:

[Where appropriate, follow Universal Precautions]

[AMPHYL®] [This product] is intended to help prevent protein matter from hardening on instruments and to help reduce exposure to pathogens during the decontamination process.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

[NOTE: Before using [AMPHYL®] [this product], consult the instrument manufacturer's instructions for care and disinfection of their instruments.] [[AMPHYL®] [This product] may cause damage to certain types of plastic trays. Refer to manufacturer's instructions for proper use.]

FOR DISINFECTION OF <u>NON-CRITICAL</u> SURGICAL AND DENTAL INSTRUMENTS [AND DUIPMENT]:

All instruments and devices must be thoroughly cleaned to remove excess debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. Apply or immerse instruments in AMPHYL[®] solution for 10 minutes to wet all surfaces thoroughly. Flush and fill the lumen of hollow instruments/equipment, avoiding entrapment of air bubbles. If instruments are to remain in the solution for substantially longer periods of time, add 1 gram of sodium bicarbonate to each quart of solution; stir to dissolve completely. Also add 2 oz. of Isopropyl alcohol per quart of solution to maintain clarity. Remove and rinse instruments. Wipe dry or allow to air dry prior to use or further processing. Change solution as needed when the solution becomes diluted or visibly soiled.

Note: Critical and semi-critical devices must be followed by appropriate sterilization or high-level disinfection process.

OR HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) ACTIVITY (Use at 0.5% Dilution – See Dilution Chart):

KILLS [HUMAN IMMUNODEFICIENCY VIRUS] [(HIV-1)] (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS

in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood/body fluids, use disposable latex gloves, gowns, masks or eye coverings.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of AMPHYL[®].

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood/body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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CONDUCTIVE FLOORS:

Certain areas of a hospital or an industrial plant require that a safe level of conductivity be maintained on the floors. The established levels of safe conductivity are between 25,000 - 1,000,000 ohms. Electric discharges must be dissipated rapidly to avoid static discharges that might affect flammable materials, such as anesthetics or sensitive electrical equipment. Using improper disinfectants or detergents can cause a residue formation which can impair conductivity. AMPHYL® [This product] has no effect on the resistant properties of conductive flooring as per the requirements of the National Fire Protection Association, NFPA-99-1993, Chapter 12, Section 12-4.1.3.8. Test results are available upon request.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals.

DANGER: Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. "Year protective eye wear and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with Lap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID		
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 	
If on skin or	Take off contaminated clothing.	
clothing	 Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. 	
If swallowed	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person 	
	CONTACT NUMBER	
Have the prod	omments or In case of an emergency call toll free (1-800-677-9218). uct container or label with you when calling a poison control center or ng for treatment.	
	NOTE TO PHYSICIAN:	
Probab	le mucosal damage may contraindicate the use of gastric lavage.	

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{For sizes 1 gallon or less}

STORAGE/DISPOSAL

Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly with water and detergent. [Wrap and] Discard in trash.

{For sizes over 1 gallon}

STORAGE/DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in areas inaccessible to small children. Keep securely closed.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

or sizes 5 gallons or more}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[This label is printed on __% recycled paper (__% post-consumer).]

[Please encourage your state and local authorities to establish a recycling program so that this [container] [bottle] [pail] [drum] can be recycled.]

NOTICE: This product contains a chemical known to the State of California to cause cancer.

MPHYL[®] is part of a system of infection control products provided by Reckitt Benckiser, Inc. People respect me AMPHYL[®] Brand name for providing high quality and trusted surface disinfection and gain the added benefit of a clean, sanitary environment.

Questions? Comments? Call 1-800-677-9218.

[Monday – [thru] Friday, 8:45 a.m. – [to] 4:30 p.m. [Eastern time].]

[Visit us at www.reckittprofessional.com]

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